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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,208	01/26/2001	Juan F. Medrano	407T-923710US	7351
22798	7590	12/16/2003	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			SHUKLA, RAM R	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/771,208	Applicant(s) MEDRANO ET AL.	
	Examiner Ram R. Shukla	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-22 and 27-36 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-22 and 27-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response and amendments filed 8-15-2003 is acknowledged.
2. Claims 1-7, 23-26 and 37-76 have been cancelled.
3. Claims 8-22 and 27-36 are pending and under consideration.
4. The objection to the specification is withdrawn in view of the applicants' arguments.
5. In view of applicants' arguments and insistence, the references 2-6 of the information disclosure statement filed 8-29-02 have been initialed. However, their relevance to the instantly claimed invention could not be considered.
6. Claim Objections to claims 8-22, 27-36 and 29 has been withdrawn in view of applicants' arguments.
7. The rejection of claims 12-22 under 101 has been withdrawn in view of the amendments to these claims.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
9. The written description rejection of Claims 11-22 and 27-36 is maintained for reasons of record set forth in the previous office action of 2-11-2003.

An inadvertent error in using the enablement form paragraph in place of the written description form paragraph is acknowledged and applicants' indication of the error is appreciated.

Response to Arguments

Applicant's arguments filed 8-15-2003 have been fully considered but they are not persuasive. Applicants arguments that by producing the knockout mouse they are in possession of the entire genus of mammals is not persuasive because in view of the unpredictable nature of the transgenic technology as discussed in the previous office action (see the arts cited in the previous office action), an artisan could not predict that any knockout mouse could have been viable or what would have been the identifying characteristics of the representative number of species of the claimed genus. Examiner is aware of the fact that the written description requirement does not require the applicant to describe exactly the subject matter claimed. Applicants' attention is drawn to MPEP

Which states:

(one must define a compound by "whatever characteristics sufficiently distinguish it").
"Compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed. " Enzo Biochem, 296 F.3d at 1324, 63 USPQ2d at 1613. (see MPEP 2163).

And in the instant case making transgenic mammals is unpredictable and the phenotype of a transgenic mouse and rat made by same method cannot be predicted. Therefore, one could not predict whether the phenotype of the mouse will be present in any other mammal. Applicants did not present any evidence that they had possession of the entire genus of the claimed invention.

Therefore, the limited disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the huge genera recited in the claims at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genera.

10. Claims 8-22 and 27-36 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a homozygous knockout mouse

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wherein both the alleles of the endogenous Socs2 gene in the genome of the mouse have been disrupted by inserting an expression cassette and wherein the knockout mouse is characterized by a large size and increased body weight and lack of functional Socs2 protein and a method of producing the knockout mouse, does not reasonably provide enablement for the other recited embodiments for reasons of record set forth in the previous office action of 2-11-2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

Applicant's arguments filed 8-15-2003 have been fully considered but they are not persuasive. Applicants arguments that Cameron article does not bear on the production of knockout animals is misplaced since it discusses the unpredictability of the art of transgenesis in general. Next, applicants argued that culturing and maintaining ES cells do not negative the invention and that an artisan could be make knockout animals using any cell, including somatic cells and then they cite articles for making mammals. While the relevance of these articles to the instant application could not be determined since the applicants did not provide copies of these articles, it is reiterated that the art of making any knockout mammals is not routine as discussed in the previous office action and the applicants did not provide any evidence that the art of making transgenic knockout mammals was routine and the method used in making one mammal could be used in making another mammal with same characteristics. Contrary to applicants' arguments, the specification as filed fails to provide enabling disclosure to make the claimed invention commensurate with the entire scope of the claims. Regarding, applicant's arguments about undue experiment analysis, applicants are reminded that such an analysis was performed in the previous office and applicants have not provided any evidence except for arguments.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 8-11, 13, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record set forth in the previous office action of 2-11-2003.

As noted in the previous office action, claims 8 and 13 are vague and indefinite because it is unclear as to what is meant by the term "a high growth phenotype".

Response to Arguments

Applicant's arguments filed 8-15-2003 have been fully considered but they are not persuasive. Applicants have argued that the term "high growth phenotype" is a term used in the art and is well known and cite an article by Horvat and Medrano et al. However, applicants' arguments are not persuasive and the article is not relevant to the instant case, since it discusses "high growth locus" which has nothing to do with "high growth phenotype". Applicants did not provide any evidence as to what was encompassed by the term and the specification does not provide definition of the term.

It is noted that claim 28 also recites the limitation and therefore is subjected to the same rejection.

13. No claim is allowed.

14. Allowable subject matter: Following invention will be allowable"
A homozygous knockout mouse wherein both the alleles of the endogenous Socs2 gene in the genome of the mouse have been disrupted by inserting an expression cassette and wherein the knockout mouse is characterized by a large size and increased body weight and lacks functional Socs2 protein and a method of producing the knockout mouse.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

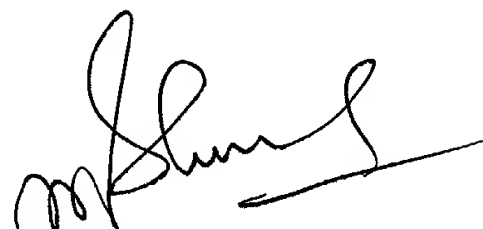
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

Please note that effective January 13, the offices for Examiner Shukla, SPE Reynolds and LIE William Phillips will move to the new USPTO location in Alexandria, VA and their phone numbers will change. The new phone numbers will be as follows:

Ram Shukla: **(571) 272-0735**

Deborah Reynolds: **(571) 272-0734**

William Phillips: **(571) 272-0548**



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632